

### **REMARKS**

In the Office action, the examiner noted that claims 1-68 were pending in the application, claims 14-68 were withdrawn from consideration, and claims 1-13 were rejected. Claims 1-13 have been amended to address the rejections and in accordance with the agreement reached in the January 13, 2009 telephone interview with the examiner.

#### **Claim Rejections**

##### **Rejections under 35 U.S.C. § 102**

Claims 1, 2, 6, and 7 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,320,093 to Raemer. The Applicant submits the claims as amended are not prima facie anticipated by Raemer.

With regard to claim 1, the examiner states that “Raemer does provide a source of pressurized air (see col. 4 lines 55-67)”. Nowhere does the disclosure of Raemer mention pressurized air. As stated in the remarks of the Applicant’s amendment before the final Office action, “the anesthesia gas [‘fresh gas’] of Raemer is not the same as the pressurized air of the present invention”. Air is “a colorless, odorless, tasteless, gaseous mixture, mainly nitrogen (approximately 78 percent) and oxygen (approximately 21 percent) with lesser amounts of argon, carbon dioxide, hydrogen, neon, helium, and other gases” (Answers.com dictionary). “Air” as commonly known and as used in the art is sourced directly from the atmosphere of the Earth and is inexpensive to collect and pressurize. By contrast, anesthesia gas is typically pure oxygen mixed with one or more of nitrous oxide, sevoflurane, desflurane, isoflurane, halothane, or some other gaseous anesthetic agent. Raemer specifically mentions the oxygen–nitrous oxide mixture (column 4, lines 58-60). To make the Applicant’s claim 1 read on the cited reference, the examiner must use an overly broad interpretation of “air” to mean “any gas mixture”, or must creatively interpret the anesthesia gas of Raemer as using air as an anesthesia gas. The Applicant respectfully submits that the latter case doesn’t make sense because any anesthesia machine utilizing air as its anesthesia gas would not function as intended—and in any case would not be the “standard anesthesia machine” recited by Raemer (column

4, line 57). As to the former case, the Applicant can only aver that "air" as used in the claims is to be interpreted under its common meaning, and, identically, the meaning that would be construed by those skilled in the art: "atmospheric air or a gas composition substantially similar thereto", and not under a broader metaphorical meaning such as "any gas composition".

The Applicant also notes here, as was noted in the remarks to the response to the prior Office action, that Raemer does not teach or suggest use of substantially low concentrations of CO<sub>2</sub>; moreover, the concentration of CO<sub>2</sub> delivered to the patient is not measured in the invention of Raemer. The examiner states that "Raemer does disclose measuring concentration of CO<sub>2</sub> in a gas mix delivered to the patient (see col. 5 lines 5-15)". Nowhere does Raemer teach or suggest measuring the concentration of CO<sub>2</sub> in a gas mix delivered to the patient. In particular, the passage cited by the examiner only suggests "a negative feedback control system and method which utilizes the partial pressure of the end tidal CO<sub>2</sub> expired by a patient to control the quantity of CO<sub>2</sub> which is delivered to the inspiration line 12 of breathing circuit 10". As stated in the remarks accompanying the amendment before the final Office action, "Raemer only discloses measurement of expired/exhaled CO<sub>2</sub>, and does not suggest measuring concentration of CO<sub>2</sub> in a gas mix delivered to the patient". Examination of the closed-loop feedback control of the invention of Raemer shows it to be incapable of measurement of the concentration of CO<sub>2</sub> in a gas mix delivered to the patient. In Raemer, with reference to FIG. 1, the CO<sub>2</sub> add controller 52 governs the addition of CO<sub>2</sub> to the gas mix delivered to the patient by operating a pair of time-controlled valves 37 which permit CO<sub>2</sub> to mix with the anesthesia gas in mixing zone 32 (see column 5, lines 15-27). If Raemer were to measure the concentration of CO<sub>2</sub> in this gas mix delivered to the patient, the measurement would need to take place either within this mixing zone, or at some part of the circuit downflow of the mixing zone before being introduced to the patient. However, as Raemer discloses, the only sensor therein is a flow meter placed in the mixing zone (FIG. 1 and column 7, lines 37-53). While this sensor is a safety measure intended to ensure that the patient is not receiving solely CO<sub>2</sub>, it does not and cannot do so by measuring the CO<sub>2</sub> concentration in the mixing zone. This sensor is intended only to check that the flow of anesthetic gas does not fall to an unsafe level. Among sensor

modalities mentioned by Raemer for this purpose are a “self-heated thermistor flow meter with an accuracy of about  $\pm 20\%$ ”, “thermal transport, momentum (vane), vortex precession, or Poiseuille's law”. None of these modalities is inherently capable of measuring CO<sub>2</sub> concentration, or even determining it by computing flow volumes.

In addition, Raemer does not teach nor disclose a PAP device for sleep therapy as claimed for delivering low concentrations of carbon dioxide to a patient or subject during sleep.

With regard to claim 2, the examiner alleges that “Raemer teaches an apparatus wherein the assembly includes a positive airway pressure module for providing the pressurized air”. Raemer, however, does not teach a positive airway pressure (PAP) module for sleep therapy; rather, Raemer teaches a conventional ventilator with a bellows, and in any case, the ventilator of Raemer is not providing pressurized air but is instead driving the mechanical ventilation of anesthetic gas to the anesthetized patient. A ventilator differs greatly from a PAP in both construction and function, and a person skilled in the art could readily distinguish them. The ventilator 22 of Raemer is not even disclosed as being a component of an anesthesia machine 28, which, in Raemer, is the source of the anesthetic gas (which the examiner mistakes for air). Thus in Raemer, the ventilator cannot be for providing the pressurized air—rather, it aids in the circulation of the anesthetic gas (and expired gas).

Claims 6 and 7 depend from claim 1 and inherit its patentable distinction over the cited publication.

Given the reasons set forth above, the Applicant respectfully requests withdrawal of these rejections.

### **Rejections under 35 U.S.C. § 103**

Claims 4, 5, 8, 9, 11, 12 and 13 were rejected under 35 U.S.C. § 103(a) as being obvious in light of U.S. Patent No. 5,320,093 to Raemer. The Applicant submits the claims as amended are not prima facie obvious in light of these rejections.

With regard to claims 8, 9, and 13, as submitted in the remarks drawn to the § 102 rejections, Raemer does not disclose a method for providing substantially low concentration of carbon dioxide; it is impossible to determine the concentration of carbon

dioxide provided by the invention of Raemer as Raemer does not offer a method for measuring the concentration of carbon dioxide in the gas mix provided to the patient. Further, as discussed in the remarks accompanying the reply to the previous Office action, Raemer does not teach or suggest that his gas mix may have stabilizing effects on target respiratory systems, but rather, is aimed at restoring ventilatory drive (i.e., the balance between hyperventilation and hypoventilation following the cessation of self-governed breathing during anesthesia). With regard to claim 9, the above remarks concerning the distinction between a PAP and a ventilator apply: the ventilator disclosed by Raemer is not the substantial equivalent of a PAP either in construction or in function here.

With regard to claims 4, 5, 11 and 12, which claim specific concentrations of CO<sub>2</sub> in the gas mix supplied to the patient, the examiner admits that Raemer does not quantitatively disclose concentrations of carbon dioxide in the gas mix. The examiner states that "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Raemer's invention by providing carbon dioxide in the gas mix that is less than 2% in order to provide the cleanest gas possible, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art." The Applicant submits that this "official notice" assertion is doesn't make sense, is untrue, and the examiner provides no evidence of this.

The assertion doesn't make sense because if the intent of the claimed invention were to "provide the cleanest gas possible", as alleged by the examiner, carbon dioxide would be omitted from the gas mix altogether, as carbon dioxide is a waste product of respiration and is not required by the body under conditions of normal respiratory stability. The intent of the invention is not to "provide the cleanest gas possible", but rather to provide carbon dioxide in substantially low concentrations so as to provide a therapeutic effect on respiratory stability. As averred in the specification of the application, "Prior to Applicant' discovery of such, use of CO<sub>2</sub> was not considered effective in doses below a concentration of 2%."

The "official notice" assertion is untrue because, as averred in the specification, "the stabilizing properties [of CO<sub>2</sub>] at low doses (less than 2%) when given in

conjunction with PAP as discovered by Applicant are heretofore not well documented or known. No equipment is currently available to deliver CO<sub>2</sub> and pressurized air in precisely metered combinations, either in a clinical or home setting. Precise metering of these gases is essential for therapeutic use since both gases, and especially CO<sub>2</sub>, have the potential for adverse side effects if an overdose is given. Metering must be maintained over a range of demand conditions.” Use of this precise metering is not of “routine skill in the art” and the invention claimed was not a discovery of “optimum or workable ranges”.

The examiner has also failed to introduce factual evidence supporting this “official notice” assertion. The MPEP requires the examiner to “provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge [or what is ‘routine skill in the art’ as alleged by the examiner].” See MPEP § 2144.03 B. The MPEP also requires the examiner to “‘point to some concrete evidence in the record in support of these findings’ to satisfy the substantial evidence test. If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding.” MPEP § 2144.03 C (emphasis added).

The Applicant suggests that what would have been obvious to a person of ordinary skill in the art at the time of the invention must be in the personal knowledge of the examiner, and request that he therefore with his next Office action submit an affidavit detailing as specifically as possible the personal knowledge upon which his rejection is based. See 37 C.F.R. § 1.104(d)(2).

Claims 3 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Raemer in view of U.S. Patent No. 5,975,078 to Pauley. The Applicant submits the claims as amended are not prima facie obvious in light of these rejections. As stated in the remarks of the reply to the prior Office action, “Neither Raemer nor Pauley, alone or in combination, mention therapeutic use of substantially low concentrations of CO<sub>2</sub> or the combination of substantially low concentrations of CO<sub>2</sub> and pressurized air to form a respiratory stabilizing gas mix as recited in base Claims 1 and 8.” The Applicant also notes for the record that the disclosure of Pauley does not teach an apparatus that

JAN 16 2009

provides a PCVSM that includes an incubator, a tent, a facemask, and a nasal cannula, as alleged by the examiner. Pauley only discloses a facemask.

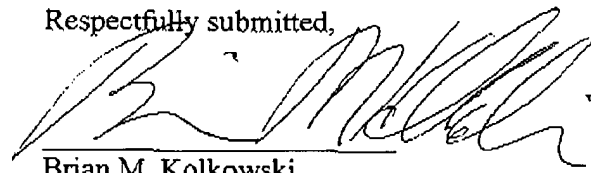
Given the reasons set forth above, the Applicant respectfully requests withdrawal of these rejections.

**CONCLUSION:**

The Applicant respectfully submit that this application is in condition for allowance and that action is earnestly solicited.

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Respectfully submitted,



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